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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/477, 147	06/07/95	LIVINGSTON	P 43016-D/JPW/

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HM22/1005

EXAMINER

DUFFY, P

ART UNIT	PAPER NUMBER
1645	dc

DATE MAILED:

10/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>08/477,147</b>	Applicant(s) <b>Livingston et al</b>
	Examiner <b>Patricia A. Duffy</b>	Art Unit <b>1645</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1)  Responsive to communication(s) filed on Jul 23, 2001.

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

#### Disposition of Claims

4)  Claim(s) 109-122 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 109-122 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

15)  Notice of References Cited (PTO-892)      18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)      19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_      20)  Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Amendment*

1. The response and amendment filed 17-23-01 has been entered into the record. It is noted that claims 102-108 were previously pending and not claims 102-120. Accordingly, claims 102-108 have been canceled and new claims 121-134, submitted with the response of 7-23-01, have been renumbered 109-122 respectively. Claims 109-122 are now pending and under examination.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

### *Rejections Withdrawn*

3. The rejection claims 71-97 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn based on Applicants' amendment.
4. The rejection of claims 71-88 under 35 U.S.C. 103(a) as being unpatentable over Livingston et al (Cancer Research, 49:7045-7050, 1989) in view of Irie et al (U.S. Patent No. 4,557,931, published December 10, 1985) and Ritter et al (Cancer Biology, 2:401-409, 1991) is withdrawn based on Applicants' amendments.
5. Applicants recently filed a request for a corrected filing receipt indicating that the instant application was a 371 of PCT/US/9400757 and a CIP of 08/009,268 filed 01/22/93, now abandoned. It is noted that the instant application 08/477,147 WAS NOT filed under 37 US 371. The examiner notes that applicants have filed a request for another corrected filing receipt on April 17, 2001 requesting the correction as above be made to correspond to the correct priority under 120. This application will be forwarded to the corrections branch for appropriate correction. It is further noted that the first line of the specification is correct.

### *Rejections/Objections Maintained Double Patenting*

6. Claims 109-122 are *provisionally rejected* under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 65-71 and 77 of copending Application No. 08/477,097. Although the conflicting claims are not identical, they are not patentably distinct from each other because they all claim conjugates by means of conjugating proteins to gangliosides through the ceramide portion and thus the particular method species drawn to GM2 or GM3 claimed in the copending application would anticipate the instant genus composition claims.

Applicants' argue that the provisional rejection should be allowed to drop and that the instant claims be allowed to issue, pursuant to MPEP section 804. Since the instant claims are not allowable, the provisional double patenting rejection is maintained for reasons already made of record.

7. Claims 109-122 are *provisionally rejected* under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 66-72 of copending Application No. 08/475,784. Although the conflicting claims are not identical, they are not patentably distinct from each other because they all claim conjugates by means of conjugating proteins to gangliosides through the ceramide portion and thus the particular method species claimed in the copending application would anticipate the instant genus composition claims.

Applicants' argue that the provisional rejection should be allowed to drop and that the instant claims be allowed to issue, pursuant to MPEP section 804. Since the instant claims are not allowable, the provisional double patenting rejection is maintained for reasons already made of record.

8. Claims 109-122 are *provisionally rejected* under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 80-86 and 92-96 of copending Application No. 08/196,154. Although the conflicting claims are not identical, they are not patentably distinct from each other because they all claim conjugating proteins to gangliosides through the ceramide portion and thus the particular method species claimed in the copending application would anticipate the instant genus composition claims.

Applicants argue that the provisional rejection should be allowed to drop and that the instant claims be allowed to issue, pursuant to MPEP section 804. Since the instant claims are not allowable, the provisional double patenting rejection is maintained for reasons already made of record.

9. Claims 109-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Livingston et al. (Cancer Research, 149:7045-7050, 1989) in view of Ritter et al. (Seminars in Cancer Biology, 2:401-409, 1991), Liane et al (Journal of Biological Chemistry, 249(14):4460-4466, 1974), Livingston et al. (U.S. Patent No. 5,102,663), Ritter et al. (Immunobiol, 182:32-43, 1990), Kensil et al.(The Journal of Immunology, 146(2):431-437, 1991), and Marciani et al. (Vaccine, 9:89-96, 1991) and Uemura et al (J Biochem, 79(6):1253-1261, 1976) is maintained for reasons made of record in Paper No. 20, mailed 4-11-00.

Applicants again argue that the combination does not teach nor suggest Applicants claimed invention. Applicants argue that the combination fails because Ritter (1991) fails to teach the means of chemical coupling. This is not persuasive, the means of chemical coupling of gangliosides was known to the art, the key teaching of Ritter (1991) is that one would expect a better response by means of coupling the ganglioside to the KLH. Ritter (1991) provides exquisite motivation to make conjugates of gangliosides and KLH with the expectation of better immunogenicity. Applicants misrepresent the examiners reliance of Ritter (1990). Ritter 1990 was cited solely for the teaching that GD3 lactone is more immunogenic than GD3 and was for support of the substitution of the lactone for the GD3 as combined and was never cited to represent linkage though ceramide. Applicants misdirection of the rejection is not understood by the examiner. Applicants apparently argue teachings not relied upon by the examiner. The modification is of the composition of the Livingston et al, not of Ritter (1991) or Ritter (1990). Applicants also argue that Liane et al does not supply what is missing form the primary reference. This is not persuasive, Liane et al teaches conjugation by means of the C-4 carbon. While Helline et al (Exhibit A) opines that Liane et al is of limited use because "limited use of the conjugation of gangliosides to carrier proteins because it requires acetylated, methyl ester derivatives of gangliosides to avoid coupling via the sialic acid carboxyl group. In contrast to Helline's statement, Liane et al does not require deacetylation after conjugation with aminoethyl-sepharose. Helline et al therefore misrepresents the complete teachings of Liane et al. Figure 1, page 4461, provides carbodiimide linkage under standard acidic, not basic conditions. The deacetylation occurs before the linkage step and the protein is not present in basic conditions when substituted for the sepharose. This is not persuasive because the teachings of Liane et al (scheme 1

do not require deacylation of the sepharose conjugate under basic conditions as alleged by Applicants . Moreover, the use of carbodiimide under the conditions of Liane et al have long been used for coupling of peptides to carrier proteins and will not degrade the protein. As such, the rejection is maintained for reasons made of record.

*New Rejections Based on Amendment*

10. Claims 109-122 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a new matter rejection.

As to claims 109-122, Applicants point to page 32, lines 1-33 and page 12, lines 4-14 for support for the now claimed invention. This is not persuasive, the passage at page 32, lines 4-14 provide for a *specific coupling procedure at the C-4 carbon of the sphingosine moiety of the ceramide to the ε-aminolysyl group of a proteins* (ozonolysis, production of a functional aldehyde group and coupling to an ε-aminolysyl group on a protein by reductive amination). The passage at page 12, lines 4-14 in combination with the passage at page 32, lines 1-33 does not support a broad coupling of the ceramide backbone of the ganglioside at the C-4 carbon of the sphingosine moiety by any generic means to the immunogenic protein based carrier as is now claimed. The written description at pages 12 and 32 does not support by way of written description, convey that applicants had at the time of filing contemplated coupling by any means, other than *the C-4 carbon of the sphingosine moiety of the ceramide to the ε-aminolysyl group of proteins*.

Applicants' amendment provides a new genus of *specific coupling procedure at the C-4 carbon of the sphingosine moiety of the ceramide to the immunogenic protein based carrier by any means and any chemistry*. This genus concept is not supported by the specific written description. The combination of the linkage by means of the C-4 carbon is tied to coupling through the ε-aminolysyl group of a proteins. Applicants were clearly not in possession of this new genus now claimed. In re East and Harmon (CCPA) 181 USPQ 716 (May 9, 1994) is instructive here where claims of a reissue application are drawn to new matter since they broadly

recite genus of "carrier particles" which is not disclosed in original patent, which discloses only subgenus of "magnetic carrier particles" and species of "iron, ferrites, nickel, and cobalt" carrier particles. Genus now claimed is not supported by the specific species described in the specification as set forth *supra*. The genus of types of linkages to the immunogenic protein-based carrier is not supported by this specification as originally filed.

Correction is required.

*Claim Rejections - 35 USC § 112*

*Status of Claims*

11. All claims stand rejected.

*Conclusion*

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must

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conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Tuesday-Saturday from 10:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.

October 3, 2001



Patricia A. Duffy, Ph.D.

Primary Examiner

Group 1600